UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

DUSA PHARMACEUTICALS, INC. and QUEEN'S UNIVERSITY AT KINGSTON, Plaintiffs, v. NEW ENGLAND COMPOUNDING PHARMACY, INC., Defendant.	Civil Action No. 04-12703 NMG

NEW ENGLAND COMPOUNDING PHARMACY INC.'S OPPOSITION TO DUSA'S MOTION TO COMPEL INSPECTION
AND
CROSS-MOTION FOR PROTECTIVE ORDER AND COSTS

I. INTRODUCTION

Now comes the defendant, plaintiff-in-counterclaim, New England Compounding Pharmacy Inc. ("NECP") and hereby opposes DUSA's Motion to Compel an inspection pursuant to Rule 34 (the "Inspection") and hereby moves for a Protective Order prohibiting the Inspection and an ordering DUSA to reimburse NECP for the legal fees incurred as a result of having to defend against DUSA's motion, which is based upon an entirely unreasonable position.

Specifically, NECP objects to the Inspection on the grounds that it is not likely to lead to relevant or admissible evidence, because neither the condition of NECP's physical plant, nor the manner in which NECP performs its compounding processes are relevant to any claim or counterclaim in this case. As more fully set forth below,

allowing an adverse party to enter upon one's land to inspect premises is an extraordinary discovery tactic, and should only be available if the inspection will aid the search for truth in a way that is unobtainable through less burdensome means. Given the fact that DUSA continues to approach physicians in the field and make disparaging and false statements about NECP, NECP is unwilling to allow DUSA unfettered access in is workplace.

Despite NECP's timely and well founded objection, being mindful of this Court's instructions at the Scheduling Conference, NECP used its best efforts to resolve this discovery dispute, by offering two different proposals to DUSA. Unfortunately, rather than accepting one of those proposals, or offering another counter proposal, DUSA insisted on filing its motion to compel.[1]

II. LEGAL AUTHORITIES

While Rule 34 permits a party to serve another party with a request to permit entry upon land for the purpose of inspection, since entry upon a party's premises may entail greater burdens and risks than mere production of documents, a greater inquiry into the necessity for inspection may be accorded to such requests. Belcher v Bassett Furniture Industries Inc, 588 F2d 904, 26 Fed. R. Serv. 2d 546 (4th Cir VA 1978). When less burdensome forms of discovery are available, an inspection provides "small utility" in the search for truth, and must yield to those

[1] Much of DUSA's motion and accompanying Affidavit from DUSA's counsel is devoted to unleashing a generalized ad hominem attack on NECP's counsel. While it is tempting to respond to such an attack by specifically rebutting each and every specific allegation and highlighting for the Court the specific details of the difficulty NECP's counsel has had in dealing with DUSA's counsel, in the interest of focusing the Court on the real issues at hand, NECP shall not engage in this type of practice. However, for the record, NECP states that it used its best efforts to resolve this dispute without troubling the Court and at all times did so in a highly professional manner.

alternative discovery tactics. Id. (motion to compel inspection denied when information is available through deposition).

Thus, an inspection of an opponent's place of business is an extraordinary discovery tactic, one available only if the inspection will aid the search for truth to a degree unobtainable through less burdensome means. Ares-Serono, Inc. v. Organon Intern. B.V., 160 F.R.D. 1, 6 (D. Mass. 1994) (Bowler, J.) (motion to compel inspection denied when information is available through deposition).

The trial court has wide discretion in making orders for the inspection of a party's premises. Martin v Reynolds Metals Corp, 297 F2d 49, 5 Fed. R. Serv. 2d 467 (9th Cir Or 1961). This discretion is guided by considerations of policy, necessity, propriety, and expediency in the particular case at hand. Morales v Turman, 59 FRD 157, 17 Fed. R. Serv. 2d 1039 (ED Tex 1972) (when important civil rights are at issue in complex litigation, a court must make every effort to enhance the fact finding process available to both sides) (*emphasis supplied)*. The need for inspection should be clear and the degree to which the proposed inspection will aid in the search for truth must be balanced against the burdens and dangers created by inspection. Niks v Marinette Paper Co, 11 FRD 384 (D NY 1951); Belcher *Supra.* Orders requiring inspection of a party's premises must be written with precision and care to ensure the reliability of the information obtained and to protect the responding party's property. Id. Conditions may be imposed on inspections, such as limiting the number of persons conducting the inspection, the areas of the premises that are to be inspected, *See* Cox v EI Du

Pont de Nemours & Co, 38 FRD 396, 10 Fed. R. Serv. 2d 973 (D SC 1965), and limiting the time period during which inspection may take place. Morales v Turman, 59 FRD 157, 17 Fed. R. Serv. 2d 1039 (ED Tex 1972). In other words, "the degree to which the proposed inspection will aid in the search for truth must be balanced against the burden and dangers created by the inspection." *See, generally*, 10A FED. PROC., L. ED. § 26:460 (1994) ("Since entry onto a party's premises imposes greater burdens and risks than the production of documents, a more probing inquiry into the need for the inspection is warranted.")

Significantly, not only is DUSA'S Motion to Compel devoid of a single legal authority relating to requests to enter upon land for the purpose of inspection, DUSA has made no effort to show that the information it seeks is unavailable through other means of discovery. As more fully set forth below, all of the discovery sought by DUSA through an inspection is available through other means of discovery. For this reason alone, DUSA's motion must fail.

III. ARGUMENT

A. DUSA'S REQUEST FOR ENTRY AND INSPECTION IS NOT LIKELY TO LEAD TO RELEVANT ADMISSIBLE EVIDENCE BECAUSE NECP'S ALLEGATIONS DO NOT RELATE TO STATEMENTS MADE BY DUSA ABOUT NECP'S PHYSICAL PLANT, OR NECP'S COMPOUNDING PROCEDURES

Essentially, DUSA's argument can be reduced to one point: Because NECP filed a counterclaim alleging that DUSA has made false and damaging statements to third parties, DUSA is entitled to inspect NECP's premises to attempt to show that the statements DUSA made were true. This argument is flawed for several reasons: First, the

statements and actions which provide a factual basis for NECP's counterclaims do not relate in any way to statements about NECP's physical plant or compounding procedures; and secondly, DUSA's argument is completely circular, since initially it was DUSA's own conduct that caused NECP to file the counterclaim (i.e. it would be completely unfair to allow DUSA to gain the ability to enter NECP's workplace, as a direct result of their own actionable conduct.)

1. The Factual Basis of NECP's Counterclaims

NECP's Counterclaim is based on the following statements made by various DUSA representatives:

a. In Paragraph 5-6 of NECP's counterclaim, NECP alleges that DUSA has made false statements to 3rd parties based on its December 27th, 2004 press release. In that press release, Dr. Geoffrey Shulman, DUSA's President and CEO refers to DUSA bringing suit against NECP, and states, "'We have taken this action to protect our proprietary intellectual property position from pharmacies such as the NECC that are promoting and selling ALA of unknown quality from unknown sources. In addition, we intend to protect against damage to our product's reputation that might arise from the use of what could be an unsafe copy of our products...." (See DUSA's December 27, 2004 press release attached hereto as Exhibit A; *Emphasis supplied*;)

b. In Paragraphs 7-8 of NECP's Counterclaim, NECP alleges that DUSA has made false statements to 3rd parties based on its January 31, 2005 press release where DUSA once again referenced this instant litigation and repeated its allegations emphasized above. (See DUSA's January 31, 2005 press release attached hereto as Exhibit A).

c. On at least one occasion, a DUSA representative told one of NECP's accounts located in Massachusetts that "New England Compounding Center, was a group of misleading liars" and that NECP was "being sued by DUSA for stealing

their product Aminolevulinic Acid." This DUSA representative told the NECP customer that NECP's products "suck". In addition, this DUSA representative also told this same NECP customer that "the FDA was on the brink of a huge crackdown on NECP, because NECP was giving bad medications to the people of the community".

d. On another occasion, a different DUSA representative told this same NECP customer that DUSA was "suing NECC for patent infringement" that the NECP customer "can't use their product" and that the quality of NECP's product was "suspect" and should not be relied upon.

e. An employee of one of NECP's customers located in Arizona attended a training seminar on various cosmetic procedures, and during that seminar a representative from DUSA made a presentation during which the representative from DUSA announced to the entire seminar that "any doctors" who were using compounded ALA would be "held liable and possible sued." The DUSA representative also announced that DUSA had sued NECP.

f. Another potential customer of NECP, located in Texas, was told by a DUSA representative that he could not order ALA from NECP because NECP was infringing on their patent, and that he should not order from NECP because NECP's product was inferior because it was "compounded."

g. Another NECP customer, located in Michigan, was told by a DUSA representative that "it was illegal for to use an unapproved drug" and that "the compounded medication from NECC was illegal" and that "the ALA NECP is using to compound the medication is not FDA approved and is unsafe."

Thus, NECP's claims are based on statements that can be categorized into two areas, neither of which support DUSA's argument that it is entitled to enter upon NECP's premises:

a. False injurious statements disparaging the quality of NECP's ALA product; and

b. False injurious statements disparaging the quality of the products NECP purchases to use in its compounding process, to achieve a final product (i.e. the source of NECP's product);

2. Alternative And Less Intrusive Discovery Methods

With respect to category one, the least intrusive and most effective way for DUSA to receive discoverable information to test the quality of NECP's products is to receive actual samples of NECP's ALA product, which DUSA can test in its own laboratory, on its own time and in its own way. This offer was made during the course of discussions among counsel and was rejected by DUSA's counsel. With respect to the second category, through deposition or document requests DUSA can obtain information about the companies from which DUSA purchases the elements used in its compounding process, and/or obtain actual samples of these "source" elements to test them in whatever way DUSA wishes. If DUSA did this, it would learn that one hundred percent of the manufacturers NECP purchases its compounds from are FDA approved manufacturers. This offer was also rejected.

It is significant that DUSA rejected these alternative means of discovery, which would have achieved DUSA's purported goal of discovering whether DUSA's injurious statements were false. Since the filing of NECP's counterclaims DUSA has continued to commit tortious acts, by making a variety of false statements both to and about NECP, as well as continuing to flood the marketplace with false and misleading information as to the scope of DUSA's patents. As recently as this week, a customer of NECP informed NECP that it had received a flyer from DUSA containing false information designed to bully the customer into purchasing ALA products from DUSA and not NECP. (See

Exhibit B which falsely states that DUSA has a patent on the drug ALA, when in fact DUSA does not have a patent on the drug, rather a patent on an applicator called "Levulan Kerastick".)

Thus, it is transparently clear that DUSA's stated reason for the Inspection is merely pretextual and that the real reason DUSA wishes to gain access to NECP's workplace is to arm DUSA representatives in the field with more ammunition to attempt to poison NECP's business, by continuing to mis-state the law and the facts about NECP's compounding business and doctors' abilities to prescribe and purchase ALA products from NECP.

In short, an Inspection of NECP's premises is wholly irrelevant to any issues raised by NECP's counterclaims; DUSA has not exhausted alternative and less intrusive discovery methods; and given the DUSA's past, present and continuing conduct with respect to attempting to poison NECP's existing and potential business relationships, DUSA's motion should be denied.

B. NECP'S EFFORTS TO RESOLVE THIS DISPUTE AND DUSA'S REFUSAL TO ACCEPT REASONABLE CONDITIONS

Within the time frame allowed by Rule 34, NECP objected to DUSA's Request For Entry Upon Land, by serving a written response which objected to the Inspection on the grounds that the Inspection was not likely to lead to relevant admissible evidence (See Exhibit C). Therefore, despite DUSA's arguments to the contrary, NECP fully preserved its objection to the Inspection on the same grounds raised in this Opposition. However, in the interest of resolving this dispute without the necessity of Court intervention, NECP suggested certain conditions designed to narrow the terms of the Inspection ("NECP's

Conciliatory Conditions"). This was accomplished through two different letters and several phone calls. Both letters explicitly state that NECP's Conciliatory Conditions were being offered "without waiving any previous objections" (See Exhibit D). Despite this clear language, DUSA argues that by offering these Conciliatory Conditions NECP has conceded or waived its objection to the Inspection. This argument is disingenuous and should weigh heavily on this Honorable Court's decision as to which party it should asses costs against.

1. Limiting the Area of the Inspection

During the course of the discussions with counsel, DUSA was informed that the small miniscule amounts of compounds used to mix NECP's ALA based products were stored in a small refrigerator within the compounding laboratory and as such, the only area that DUSA would be permitted to inspect was the refrigerator where the elements were stored and the laboratory itself. This representation was reiterated in NECP's letter of August 18, 2005:

> The inspection will be limited to NECP's Compounding Laboratory used for compounding ALA (the "Compounding Lab"). This is a single room where NECP's Flowscience Hepafiltration hood is stationed, (containing an electronic analytical balance scale) and NECP's refrigeration system. (See Exhibit D)

In addition, NECP sought to prevent DUSA from opening various cabinets within the compounding laboratory that contain items completely unrelated to any element of NECP's compounding of ALA product. NECP offered to certify that the cabinets contained material wholly unrelated to ALA product, which DUSA initially agreed would suffice. Apparently, DUSA no longer wishes to accept that certification; however,

DUSA has not articulated a valid reason why they believe they are entitled to examine areas which are unrelated to ALA. As specifically noted above, DUSA's ongoing tortious conduct continues and therefore NECP is unwilling to allow DUSA to inspect areas of its premises unrelated to ALA. This condition was a reasonable one and DUSA's refusal to accept this term speaks volumes as to DUSA's real motivation for requesting this Inspection.

2. Mutual Inspections

Another element of NECP's Conciliatory Conditions was that DUSA agree to allow NECP inspect its facilities under the same Conciliatory Conditions. In discussions with DUSA's counsel, DUSA's sole reason for its reluctance to agree to this term was that DUSA had not alleged claims where the veracity of statements to third parties were at issue and therefore the conditions under which DUSA manufactured ALA were not relevant. This argument is without merit because the connotation of virtually each and every statement giving rise to NECP's counterclaim is that DUSA's product is safe and effective and NECP's product is not. In other words, DUSA's actionable conduct has not taken place in a vacuum, to be analyzed without context. One of the clear implications of virtually all of DUSA's injurious statements is that the quality of DUSA's product is superior to NECP's product. Simply put, if the conditions under which NECP compounds are relevant to the truth of the statements made by DUSA, then the conditions under which DUSA manufactures are just as relevant. Below are the statements providing a factual basis for NECP's counterclaim, with the context highlighted:

- "We have taken this action to protect our proprietary intellectual property position from pharmacies such as the NECC that are promoting and selling ALA of

unknown quality from unknown sources. In addition, we intend to protect against damage to our product's reputation that might arise from the use of what could be an unsafe copy of our products...." (See DUSA's December 27, 2004 press release attached hereto as Exhibit A; *Emphasis supplied*;)

- These same emphasized portions of the statements above were repeated in DUSA's January 31, 2005 press release. (See DUSA's January 31, 2005 press release attached hereto as Exhibit A).
- "New England Compounding Center was a group of misleading liars" and that NECP was "being sued by DUSA for stealing their product Aminolevulinic Acid." NECP's products "suck". In addition, this DUSA representative also told this same NECP customer that "the FDA was on the brink of a huge crackdown on NECP, because NECP was giving bad medications to the people of the community".
- DUSA was "suing NECC for patent infringement" that the NECP customer "can't use their product" and that the quality of NECP's product was "suspect" and should not be relied upon.
- "Any doctors" who were using compounded ALA would be "held liable and possible sued." The DUSA representative also announced that DUSA had sued NECP.
- A customer "could not order ALA from NECP because NECP was infringing on their patent, and that he should not order from NECP because NECP's product was inferior because it was "compounded."

Therefore, *assuming arguendo*, that an inspection is an appropriate form of discovery to aid DUSA in defending against the counterclaims, then an inspection of DUSA's premises, to assist NECP in proving their counterclaims, is also appropriate. Moreover, since NECP carries the burden of proof on its counterclaims, to allow DUSA

to inspect NECP's premises, but not allow NECP to inspect DUSA's premises would be completely inequitable.[2]

3. NECP's Request That DUSA Explicitly Recognize That By Agreeing To Allow An Expert In The Field Of FDA Regulation To Participate In The Inspection That NECP Had Not Waived Its Right to Later Object To That Expert's Testimony On Relevance Grounds.

From the outset of this litigation, NECP has attempted to explain to DUSA that a compounding pharmacy is not a drug manufacturer (as DUSA is) and therefore is not subject to the same FDA regulations as DUSA, but instead is regulated by the Massachusetts Board of Registration in Pharmacy.

In 2002, the FDA issued a Compliance Policy Guide Manual for the Pharmacy Compounding industry in which the FDA declared that:

> FDA recognizes that pharmacists traditionally have extemporaneously compounded and manipulated reasonable quantities of human drug upon receipt of a valid prescription for an individually identified patient from a licensed practitioner. This traditional activity is not the subject of this guidance. With respect to such activities, 21 U.S.C. 360 (g)(1) exempts retail pharmacies from the registration requirements of the Act. The exemption applies to "Pharmacies" that operate in accordance with state law and dispense drugs "upon prescriptions of practitioners licensed to administer such drugs to patients under the care of such practitioners in the course of their professional practice, and which do not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail" (emphasis added). See also 21 U.S.C. §§ 374(a)(2) (exempting pharmacies that meet the foregoing criteria from certain inspection provisions) and 353 (b)(2) (exempting drugs dispensed by filling a valid prescription from certain misbranding provisions).
>
> (Guidance for FDA Staff and Industry Compliance Policy Guides Manual, Sec.460.200 Pharmacy Compounding, U.S. Department of Health and

[2] DUSA's argument that NECP has not served a request to enter upon land is exactly the point NECP has articulated in Section A (2) on Pages 7-8 above. As of the writing of DUSA's motion and this Opposition, neither party has taken a single deposition nor received responses to discovery requests. Thus, at this juncture neither party has exhausted less intrusive discovery tools and as such service of a request to enter upon land for the purposes of inspection is unwarranted.

Human Services, Food and Drug Administration, Office of Regulatory Affairs, Center for Drug Evaluation and Research, May 2002 pages 2-3, including footnote 2 attached hereto as Exhibit E)

Despite these attempts and despite this clear fact, DUSA continues to refuse to recognize this distinction and continues to approach this case as if the compounding industry is treated by the FDA in the same manner as the FDA treats manufacturers.

The only reason this distinction arose within the context of this discovery dispute is because one of the individuals DUSA sought to include in their Inspection was an expert in the field of FDA regulation. As part of NECP's Conciliatory Conditions, NECP simply requested that if DUSA chose to include an expert in the field of FDA regulations in the Inspection, DUSA must also agree that by NECP's assent to the FDA expert's presence, NECP had not waived its right to challenge the qualifications of the expert (to testify or provide evidence by way of affidavit) on the grounds that the expert was not qualified to offer an expert opinion on material or relevant subject matter.

IV. NECP's CROSS MOTION FOR PROTECTIVE ORDER AND COSTS

For all of the foregoing reasons, NECP hereby moves this Honorable Court to issue a Protective Order prohibiting DUSA from entering upon NECP's Land and Order DUSA to reimburse NECP for the amount of reasonable attorney's fees NECP incurred in connection with the defense of DUSA's Motion to Compel. An affidavit of legal fees shall be provided to the Court at the hearing on this matter.

WHEREFORE NECP PRAYS that this Honorable Court:

1. Deny DUSA's Motion to Compel Inspection,;

2. Allow NECP's Motion For a Protective Order; and

3. Award NECP reasonable Attorney's Fees; and

4. Any other relief this Court deems just and fair.

DEFENDANT REQUESTS A HEARING ON THIS MATTER.

NEW ENGLAND COMPOUNDING PHARMACY, INC.

By its attorneys,

/s/ Daniel M. Rabinovitz

Daniel M. Rabinovitz, BBO No. 558419

Menard, Murphy & Walsh LLP

60 State Street - 34th Floor

Boston, Massachusetts 02109

(617) 832-2500

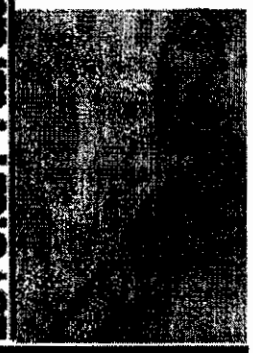
Dated: September 23, 2005

EXHIBIT A

DUSA

Innovation in Photodynamic Therapy

Levulan® Kerastick®



Physician Section
Patient Section
Investor Relations

DUSA Press Release

DUSA Pharmaceuticals, Inc. ®
For Immediate Release December 27, 2004

News
Press Releases
Press Release Archives
Articles and Presentations

DUSA PHARMACEUTICALS FILES SUIT AGAINST COMPOUNDING PHARMACY

Wilmington, MA. December 27th, 2004 - DUSA Pharmaceuticals, Inc. (NASI NMS:DUSA) reported today that it has filed a lawsuit against New England Compounding Center (NECC) of Framingham, Massachusetts alleging violatic of U.S. patent law. The suit has been filed in the United States District Court ir Boston, Massachusetts.

In addition, DUSA believes that certain actions of NECC go beyond the activiti which are permitted under the Food, Drug and Cosmetic Act, and as a result, advised the U.S. Food and Drug Administration (FDA) and local health author of its concerns.

Dr. Geoffrey Shulman, DUSA's President and CEO, stated, "'We have taken t action to protect our proprietary intellectual property position from pharmacies as the NECC that are promoting and selling ALA of unknown quality from unk sources. In addition, we intend to protect against damage to our product's reputation that might arise from the use of what could be an unsafe copy of ou products. The recent serious incidents involving the use of non-FDA approvec botulinum toxin illustrate how important it is to be proactive in this regard."

DUSA Pharmaceuticals, Inc. is a biopharmaceutical company engaged prima the development of Levulan Photodynamic Therapy (PDT) and Photodetectio (PD) for multiple medical indications, with its primary focus in dermatology. PI and PD utilize light-activated compounds such as Levulan to induce a therape or detection effect. The Company maintains offices in Wilmington, MA, Valhal NY, and Toronto, Ontario.

Except for historical information, this news release contains certain forward-lo statements that involve known and unknown risk and uncertainties, which ma cause actual results to differ materially from any future results, performance o achievements expressed or implied by the statements made. These forward-looking statements relate to the Company's belief regarding NECC activities a

its intention to protect its product's reputation and other risks identified in DUSA SEC filings from time to time.

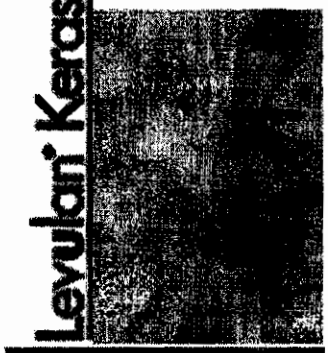
For further information contact:

D. **Geoffrey Shulman, MD**, President & CEO
or Shari Lovell, Director, Shareholder Services Tel: 416.363.5059 Fax 416.363.6602

DUSA

Innovation in Photodynamic Therapy

Levulan® Kerastick®



Physician Section
Patient Section
Investor Relations

DUSA Press Release

News
Press Releases
Press Release Archives
Articles and Presentations

DUSA Pharmaceuticals, Inc. ®
For Immediate Release January 31, 2005

DUSA PHARMACEUTICALS FILES SUIT AGAINST SECOND COMPOUNDING PHARMACY

Wilmington, MA. January 31, 2005 - DUSA Pharmaceuticals, Inc. (NASDAC NMS: DUSA) reported today that it has filed a lawsuit against The Cosmetic Pharmacy of Tucson, Arizona alleging violations of the Lanham Act for false advertising and trademark infringement, and of U.S. patent law. The suit has l filed in the United States District Court for the District of Arizona.

In addition, DUSA believes that certain actions of The Cosmetic Pharmacy go beyond the activities which are permitted under the Food, Drug and Cosmetic and as a result, it has advised the U.S. Food and Drug Administration (FDA) Arizona State Board of Pharmacy of its concerns.

On December 27, 2004, DUSA announced that it had filed a lawsuit against N England Compounding Center of Framingham, Massachusetts alleging violat of U.S. patent law.

Dr. Geoffrey Shulman, DUSA's Chairman of the Board and Chief Executive C stated, "We are filing this second lawsuit to demonstrate that we intend to pro our proprietary intellectual property position from those compounding pharma that go beyond their legal limits and that are promoting and selling ALA of un quality from unknown sources. We have an obligation to protect against dam our product's reputation that might arise from the use of what could be an un copy of our products. We intend to protect our trademarks and our goodwill, especially in light of recent events which implicate The Cosmetic Pharmacy i recent serious incidents involving the use of non-FDA approved botulinum to causing The Cosmetic Pharmacy to be restrained from committing violations Food Drug and Cosmetic Act by the United States District Court in the South District of Florida."

DUSA Pharmaceuticals, Inc. is a biopharmaceutical company engaged prim the development of Levulan Photodynamic Therapy (PDT) and Photodetecti (PD) for multiple medical indications, with its primary focus in dermatology. F and PD utilize light-activated compounds such as Levulan to induce a therap or detection effect. The Company maintains offices in Wilmington, MA, Valh

NY, and Toronto, Ontario.

Except for historical information, this news release contains certain forward-loo statements that involve known and unknown risk and uncertainties, which may cause actual results to differ materially from any future results, performance or achievements expressed or implied by the statements made. These forward-looking statements relate to the Company's belief regarding The Cosmetic Pharmacy activities and its intention to protect its product's reputation and othe risks identified in DUSA's SEC filings from time to time.

For further information contact:

D. **Geoffrey Shulman, MD**, President & CEO
or **Shari Lovell**, Director, Shareholder Services Tel: 416.363.5059 Fax 416.363.6602

EXHIBIT B

DUSA

Did you know . . .

DUSA Pharmaceuticals Levulan® Kerastick® is the only FDA-approved form of aminolevulinic acid (ALA) in the United States.

To Physicians:

Some pharmacies in the United States are currently compounding **aminolevulinic acid (ALA)** solutions and offering the formulations to physicians with instructions that these ALA products should be used to treat acne, actinic keratoses, or other conditions. **DUSA Pharmaceuticals, Inc ®**, which manufactures ALA under the trademark **Levulan® Kerastick®**, holds U.S. patents on this drug. DUSA has filed lawsuits to halt the illegal distribution of unsafe and unmonitored ALA through compounding pharmacies, and the company will continue to protect its patents aggressively.

Dermatologists who purchase or use ALA distributed by compounding pharmacies may be infringing on DUSA's Levulan® patents and exposing themselves to significant risks and liabilities. Recently, in Florida, a number of practitioners were suspended for prescribing botulinum toxin A that was obtained outside proper distribution channels. We wish to avoid any similar situation.

We trust that all physicians regard the laws, patents, and regulations that govern the Levulan® Kerastick® product as fundamental to safe practice for physicians and patients, as well as the rights of DUSA Pharmaceuticals.

Information or questions about this issue can be directed to DUSA Customer Service at 877-533-3872.

EXHIBIT C

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

DUSA PHARMACEUTICALS, INC. and QUEEN'S UNIVERSITY AT KINGSTON, Plaintiffs, v. NEW ENGLAND COMPOUNDING PHARMACY, INC., Defendant.	Civil Action No. 04-12703 NMG

NEW ENGLAND COMPOUNDING PHARMACY INC.'S RESPONSE TO DUSA'S REQUEST FOR ENTRY UPON LAND

Now comes the defendant, plaintiff-in-counterclaim, New England Compounding Pharmacy Inc. ("NECP") and hereby responds to DUSA's request to enter upon NECP'S land for purposes of inspection (the "Request").

NECP objects to the Request on the grounds that the Request is not likely to lead to relevant admissible evidence. Additionally, NECP objects to the Request because of patient privacy issues and HIPPA considerations. At this juncture, DUSA has not articulated any reason why DUSA believes an inspection of NECP's premises could lead to any relevant evidence relating to any of the elements DUSA's claims of Inducement of Infringement.

Given this complete lack of relevance, it seems clear that DUSA is merely interested in conducting a fishing expedition to attempt to discover details of NECP's manufacturing plant, in order to arm DUSA's representatives out in the field, so that those representatives can continue to make knowingly false statements about NECP to

NECP's potential customers. All of these considerations lead NECP to conclude that at this time they will not permit DUSA to enter upon their premises.

NECP has offered to discuss the Request with DUSA and while NECP is hopeful that this matter can be resolved without the assistance of the court, NECP reserves its right to raise additional arguments which become relevant as a result of any discussions with counsel for DUSA, in the event DUSA does in fact seek to burden the Court with this issue.

NEW ENGLAND COMPOUNDING PHARMACY, INC.

By its attorneys,

Daniel M. Rabinovitz, BBO No. 558419

Menard, Murphy & Walsh LLP

60 State Street - 34th Floor

Boston, Massachusetts 02109

(617) 832-2500

Dated: August 12, 2005

EXHIBIT D

MENARD, MURPHY & WALSH LLP
ATTORNEYS AT LAW

ANITA WYZAN ROBBOY
robboy@mmwl... m

August 18, 2005

Via Fax (215)-851-1420

Valerie Brand Pipano, Esq.
Reed Smith LLP
2500 One Liberty Place
1650 Market Street
Philadelphia, PA 19103

Dear Ms. Brand Pipano:

The purpose of this letter is to facilitate our "meet and confer" obligations with respect to the issue of DUSA's request to enter upon NECP's land (the "Request") and is made without waiving any previous objections, or NECP's right to supplement its prior written objections.

At the outset, please understand that NECP's counterclaim does not relate to statements made by DUSA relating to the condition of NECP's physical plant. Rather, NECP's counterclaim relates to false statements made by DUSA relating to the quality of NECP's ALA compounds and false statements relating to the source of the chemical compounds used in NECP's compounding process. If DUSA is truly interested only in facts which relate to these issues, there are more effective, less intrusive and more relevant ways to discover these facts. For example, obtaining samples suitable for laboratory analysis would be the best way for DUSA to conduct discovery relating to the quality of NECP's final product. With respect to the source of the chemicals used by NECP in its ALA compounding process, document requests, and/or deposition testimony would reveal that NECP obtains these compounds from an FDA registered chemical distribution company. Therefore, NECP is not convinced that DUSA has articulated a specific, valid reason for the requested inspection.

In addition, please be advised that the portion of your Request that seeks to examine areas related to the "manufacture, [and] fabrication" of ALA describes processes which NECP does not perform. In other words, NECP does not manufacture or fabricate ALA. Rather, NECP performs compounding services by combining compounds to produce a product in final dosage form.

Despite DUSA's failure to articulate a specific relevant reason for the inspection, in the interest of resolving this dispute without the necessity of troubling the Court, if,

and only if, DUSA agrees to the following conditions, NECP will permit DUSA to inspect the areas described below:

1. The inspection will occur during a time other than NECP's regular business hours, so as to minimize patient privacy and patient safety concerns. We would suggest an inspection beginning at 5:30 P.M. on any of the following dates: September 7, 8, 9, 12 or 13.

2. DUSA's inspection team shall consist of no more than the following individuals: one company representative; one attorney; one photographer and one videographer;

3. The inspection will be limited to NECP's Compounding Laboratory used for compounding ALA (the "Compounding Lab"). This is a single room where NECP's Flowscience Hepafiltration hood is stationed, (containing an electronic analytical balance scale) and NECP's refrigeration system.

4. Within the Compounding Lab, there are various cabinets and containers which do not relate in any way to any issue in this litigation and as such, those cabinets and containers will remain closed.

5. With respect to the storage of documents, due to the manner in which documents are stored, it is impossible to allow DUSA unfettered access into document storage areas without compromising patient privacy and violating HIPAA. However, NECP will allow inspectors to examine all of the documents which relate to the ALA compounding process, which consist of formula worksheets and refrigeration temperature logs.

6. No NECP employees shall be photographed or videotaped.

7. Finally, in order to avoid any confrontation during the inspection process, DUSA must agree that if during the inspection NECP believes DUSA is not complying with the parameters set forth above, NECP may terminate the inspection by informing the DUSA inspection team that the inspection is terminated at which time the entire DUSA inspection team will immediately vacate the premises. In the unlikely event that this occurs, the parties would have the right to seek assistance from the Court.

I look forward to discussing this proposal with you at 2:00 P.M.

Very truly yours,

Daniel M. Rabinovitz

CC: Gregory Conigliaro
Mona Patel Esq.

MENARD, MURPHY & WALSH LLP
ATTORNEYS AT LAW

DANIEL M. RABINOVITZ
drabinovitz@mmwlaw.com

August 26, 2005

Via Fax (215)-851-1420

Valerie Brand Pipano, Esq.
Reed Smith LLP
2500 One Liberty Place
1650 Market Street
Philadelphia, PA 19103

Dear Ms. Brand Pipano:

In furtherance of our discussions with respect to the issue of DUSA's request to enter upon NECP's land (the "Request") and without waiving any previous objections, or NECP's right to supplement its prior written objections, there are several key points in your letter of August 19, 2005 which merit a response.

Both your letter of August 19, 2005 and your client's entire position, ignore a simple fact which NECP made DUSA aware of long ago: NECP is not a manufacturer and thus is not regulated by the FDA. NECP is a compounding company, which is regulated by the Massachusetts Board of Registration in Pharmacy. Therefore, not only is your footnote in your August 19, 2005 letter inaccurate, but more importantly your stated reason for requesting the inspection in the first place is completely misguided and demonstrates a total lack of understanding of the compounding industry as a whole.

With respect to the numbered points in your letter of August 19, 2005, here is NECP's revised offer:

1. If the inspection occurs, it will begin at 5:30 p.m. on a mutually agreeable date in the near future.

2. NECP will allow the following individuals into its premises: one lead counsel, one local counsel, one photographer, and one videographer. However, if DUSA insists on bringing an expert in the field of FDA regulations, DUSA must also agree that by NECP assenting to this, NECP has not waived its right to challenge the qualifications of the expert (to testify or provide evidence by way of affidavit) on the grounds that the expert is not qualified to offer an expert opinion on material or relevant subject matter. Contrary to the statement in your August 19th letter, NECP's failure not to object to the Acknowledgement of Protective Order has absolutely no bearing on NECP's right to object to that expert to enter upon its land, nor on NECP's right to object to any evidence offered by the expert. Simply put, as a compounder,

the FDA's regulations and standards are completely irrelevant to any issue in this case.

3. For the reasons set forth above, NECP can not agree to allow the inspection to occur outside of the compounding laboratory.

4. Once again, your stated reasons for wanting to open cabinets in the compounding laboratory completely misunderstands the nature of NECP's business and the nature of the compounding industry as a whole. NECP does not manufacture anything. It receives orders from physicians to fill and ship prescriptions and it does so. Previously, you indicated during a phone call that DUSA was willing to agree not to open the cabinets if NECP certified they contained items wholly unrelated to the litigation. That offer still stands.

5. We are in agreement that the inspection will not encompass the review of documents.

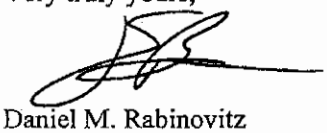
6. NECP will have a representative present to direct the inspection, but DUSA must agree not to photograph any NECP employee, whether "purposefully" or otherwise.

7. We agree that if NECP believes DUSA has violated the terms of our agreement regarding the inspection, upon notification of this belief DUSA will leave the premises immediately.

Finally, since DUSA insists that the nature of our counterclaim has put at issue whether the conditions of NECP's compounding process are inferior to DUSA's manufacturing processes, DUSA must agree to allow NECP inspect its facilities on a mutually convenient date and under the same conditions set forth above.

I look forward to hearing from you soon.

Very truly yours,



Daniel M. Rabinovitz

CC: Gregory Conigliaro
Mona Patel, Esq.

EXHIBIT E

Guidance for FDA Staff and Industry

Compliance Policy Guides Manual

Sec. 460.200
Pharmacy Compounding

Submit written comments regarding this guidance document to the Dockets Management Branch (HFA-305), 5630 Fishers Lane, rm.1061, Rockville, MD 20852.

Additional copies of this document may be obtained by sending a request to the Division of Compliance Policy (HFC-230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or from the Internet at: http://www.fda.gov/ora/compliance_ref/cpg/default.htm

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Center for Drug Evaluation and Research
May 2002

02D-0242

GDL-1

Compliance Policy Guide

Compliance Policy Guidance for FDA Staff and Industry[1]

CHAPTER - 4

SUB CHAPTER - 460

Sec. 460.200 Pharmacy Compounding

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

INTRODUCTION

This document provides guidance to drug compounders and the staff of the Food and Drug Administration (FDA) on how the Agency intends to address pharmacy compounding of human drugs in the immediate future as a result of the decision of the Supreme Court in Thompson v. Western States Medical Center, No. 01-344, April 29, 2002. FDA is considering the implications of that decision and determining how it intends to regulate pharmacy compounding in the long term. However, FDA recognizes the need for immediate guidance on what types of compounding might be subject to enforcement action under current law. This guidance describes FDA's current thinking on this issue.

BACKGROUND

On March 16, 1992, FDA issued a compliance policy guide (CPG), section 7132.16 (later renumbered as 460.200) to delineate FDA's enforcement policy on pharmacy compounding. That CPG remained in effect until 1997 when Congress enacted the Food and Drug Administration Modernization Act of 1997.

[1] This guidance has been prepared by the Office of Regulatory Policy and the Office of Compliance in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration.

On November 21, 1997, the President signed the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) (the Modernization Act). Section 127 of the Modernization Act added section 503A to the Federal Food, Drug, and Cosmetic Act (the Act), to clarify the status of pharmacy compounding under Federal law. Under section 503A, drug products that were compounded by a pharmacist or physician on a customized basis for an individual patient were entitled to exemptions from three key provisions of the Act: (1) the adulteration provision of section 501(a)(2)(B) (concerning the good manufacturing practice requirements); (2) the misbranding provision of section 502(f)(1) (concerning the labeling of drugs with adequate directions for use); and (3) the new drug provision of section 505 (concerning the approval of drugs under new drug or abbreviated new drug applications). To qualify for these statutory exemptions, a compounded drug product was required to satisfy several requirements, some of which were to be the subject of FDA rulemaking or other actions.

Section 503A of the Act took effect on November 21, 1998, one year after the date of the enactment of the Modernization Act. In November, 1998, the solicitation and advertising provisions of section 503A were challenged by seven compounding pharmacies as an impermissible regulation of commercial speech. The U.S. District Court for the District of Nevada ruled in the plaintiffs' favor. FDA appealed to the U.S. Court of Appeals for the Ninth Circuit. On February 6, 2001, the Court of Appeals declared section 503A invalid in its entirety (Western States Medical Center v. Shalala, 238 F.3rd 1090 (9th Cir. 2001)). The government petitioned for a writ of certiorari to the U.S. Supreme Court for review of the circuit court opinion. The Supreme Court granted the writ and issued its decision in the case on April 29, 2002.

The Supreme Court affirmed the 9th Circuit Court of Appeals decision that found section 503A of the Act invalid in its entirety because it contained unconstitutional restrictions on commercial speech (i.e., prohibitions on soliciting prescriptions for and advertising specific compounded drugs). The Court did not rule on, and therefore left in place, the 9th Circuit's holding that the unconstitutional restrictions on commercial speech could not be severed from the rest of section 503A. Accordingly, all of section 503A is now invalid.

FDA has therefore determined that it needs to issue guidance to the compounding industry on what factors the Agency will consider in exercising its enforcement discretion regarding pharmacy compounding.

DISCUSSION

FDA recognizes that pharmacists traditionally have extemporaneously compounded and manipulated reasonable quantities of human drugs upon receipt of a valid prescription for an individually identified patient from a licensed practitioner. This traditional activity is not the subject of this guidance.[2]

[2] With respect to such activities, 21 U.S.C. 360(g)(1) exempts retail pharmacies from the registration requirements of the Act. The exemption applies to "Pharmacies" that operate in accordance with state law and dispense drugs "upon prescriptions of practitioners licensed to administer such drugs to patients under the care of such practitioners in the

FDA believes that an increasing number of establishments with retail pharmacy licenses are engaged in manufacturing and distributing unapproved new drugs for human use in a manner that is clearly outside the bounds of traditional pharmacy practice and that violates the Act. Such establishments and their activities are the focus of this guidance. Some "pharmacies" that have sought to find shelter under and expand the scope of the exemptions applicable to traditional retail pharmacies have claimed that their manufacturing and distribution practices are only the regular course of the practice of pharmacy. Yet, the practices of many of these entities seem far more consistent with those of drug manufacturers and wholesalers than with those of retail pharmacies. For example, some firms receive and use large quantities of bulk drug substances to manufacture large quantities of unapproved drug products in advance of receiving a valid prescription for them. Moreover, some firms sell to physicians and patients with whom they have only a remote professional relationship. Pharmacies engaged in activities analogous to manufacturing and distributing drugs for human use may be held to the same provisions of the Act as manufacturers.

POLICY:

Generally, FDA will continue to defer to state authorities regarding less significant violations of the Act related to pharmacy compounding of human drugs. FDA anticipates that, in such cases, cooperative efforts between the states and the Agency will result in coordinated investigations, referrals, and follow-up actions by the states.

However, when the scope and nature of a pharmacy's activities raise the kinds of concerns normally associated with a drug manufacturer and result in significant violations of the new drug, adulteration, or misbranding provisions of the Act, FDA has determined that it should seriously consider enforcement action. In determining whether to initiate such an action, the Agency will consider whether the pharmacy engages in any of the following acts:

1. Compounding of drugs in anticipation of receiving prescriptions, except in very limited quantities in relation to the amounts of drugs compounded after receiving valid prescriptions.

2. Compounding drugs that were withdrawn or removed from the market for safety reasons. Appendix A provides a list of such drugs that will be updated in the future, as appropriate.

---

course of their professional practice, and which do not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail" (emphasis added). See also 21 U.S.C. §§ 374(a)(2) (exempting pharmacies that meet the foregoing criteria from certain inspection provisions) and 353(b)(2) (exempting drugs dispensed by filling a valid prescription from certain misbranding provisions).